



## Complete Summary

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### GUIDELINE TITLE

Adherence to antiretroviral therapy among substance users.

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Adherence to antiretroviral therapy among substance users. New York (NY): New York State Department of Health; 2005 Jun. 11 p. [38 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Substance use

### GUIDELINE CATEGORY

Counseling  
Management

### CLINICAL SPECIALTY

Allergy and Immunology  
Family Practice  
Infectious Diseases  
Internal Medicine

## INTENDED USERS

Advanced Practice Nurses  
Health Care Providers  
Physician Assistants  
Physicians  
Public Health Departments  
Substance Use Disorders Treatment Providers

## GUIDELINE OBJECTIVE(S)

To provide recommendations for adherence to antiretroviral therapy among human immunodeficiency virus (HIV)-infected substance users

## TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients using illicit substances

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Establishing a strong patient-provider relationship, including trust and engagement with the provider
2. Identifying and addressing potential barriers to adherence before initiating highly active antiretroviral therapy (HAART), reassessing barriers to adherence at least every 3 to 4 months, discussing with patients the known interactions between prescribed medications and illicit substances
3. Educating patients about the safety and efficacy of methadone and buprenorphine and assessing potential interactions between HAART and methadone before and during therapy
4. Counseling patients about the need for strict adherence and the risk of viral drug resistance when adherence is compromised
5. Performing a thorough adherence assessment and obtaining antiretroviral resistance assays prior to changing a failing regimen
6. Assessing adherence using the following methods or a combination:
  - Self-report
  - Pill count
  - Pharmacy records
  - Electronic pill bottle monitors
  - Therapeutic drug monitoring
  - Directly observed therapy (DOT)
  - Modified directly observed therapy (MDOT)
  - Computer-assisted self interview (CASI) assessment
7. Improving adherence using the following intervention strategies:
  - Education and motivation
  - Simplifying the regimen and tailoring it to the patient's lifestyle
  - Management of side effects
  - Identification and treatment of depression
  - Substance use treatment
  - Involving an adherence team or monitor
  - Referring the patient to social services and mental health providers

## MAJOR OUTCOMES CONSIDERED

- Predictors of adherence to antiretroviral therapy
- Antiretroviral resistance
- The advantages and disadvantages of adherence measures

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others.

Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

##### Introduction

Clinicians should consider substance users candidates for highly active antiretroviral therapy (HAART) if they meet the medical eligibility criteria for HAART and demonstrate readiness to begin therapy by attending the majority of their appointments and expressing interest in antiretroviral therapy (ARV) treatment.

##### Key Point:

History of substance use or current substance use should not be the sole factor in withholding HAART from eligible patients. Decisions about when to prescribe HAART for eligible drug-using patients should be made on a case-by-case basis.

##### Predictors of Adherence

Key Point:

A strong patient-provider relationship, including trust and engagement with the provider, has been associated with improved ARV adherence.

Addressing Potential Barriers to Adherence before Initiating HAART

Clinicians should identify and address potential barriers to adherence before initiating HAART in human immunodeficiency virus (HIV)-infected substance users (see the Table 1 below). If clinicians elect to defer prescribing HAART while addressing potentially modifiable barriers to adherence, they should discuss this decision with the patient.

Clinicians should reassess potential barriers to adherence at least every 3 to 4 months and whenever adherence problems are identified.

Clinicians should discuss with patients the known interactions between prescribed medications and illicit substances.

Table 1 Potential Barriers to Adherence
<ul style="list-style-type: none"><li>• Active substance use</li><li>• Inadequate substance abuse treatment</li><li>• Lack of social stability (e.g., housing problems, legal issues) or social support (e.g., disrupted family and community ties, unstable relationships)</li><li>• Lack of belief in medications or denial about being HIV-infected</li><li>• Poor self-efficacy</li><li>• Regimen does not "fit" with patient's daily routine</li><li>• Untreated mental illness, particularly depression</li><li>• Side effects</li><li>• Drug-drug interactions</li></ul>

Additional Barriers to Address with Patients Receiving Concurrent Opioid Pharmacotherapy

Clinicians should educate patients who receive concurrent opioid pharmacotherapy and ARV therapy about the safety and efficacy of methadone and buprenorphine because these patients may have misconceptions regarding the safety of concurrent opioid pharmacotherapy and ARV therapy.

Clinicians should assess potential interactions between HAART and methadone before and during therapy by inquiring about oversedation and opioid withdrawal symptoms. If withdrawal symptoms are present, the primary care clinician should conduct a detailed history and facilitate a dose increase by educating the patient and communicating with the methadone provider.

Adherence and Antiretroviral Resistance

Clinicians should counsel patients before initiating ARV therapy and at routine monitoring visits during therapy concerning the need for strict adherence and the risk of viral drug resistance when adherence is compromised.

Clinicians should perform a thorough adherence assessment and obtain antiretroviral resistance assays prior to changing regimens in patients who are receiving a failing regimen (failure to demonstrate  $>1.5$ -log drop in viral load within 3 months of initiating treatment and, more importantly, failure to achieve a viral load  $<50$  copies/mL within 6 months of initiating treatment).

### Measurement of Adherence

Clinicians should assess adherence at every routine monitoring visit.

Clinicians should use finite time intervals when inquiring about and quantifying the patient's self-report. Clinicians should average responses across visits to obtain a more accurate estimate of adherence.

When assessing adherence, clinicians should use precise language that the patient can understand. In addition, clinicians should verify that patients are taking the medications as prescribed, specifically, correct medications, correct number of pills per dose, and correct number of doses per day.

#### Key Points:

- Adherence measurements averaged from repeated adherence assessments will yield a more accurate calculation of adherence than one-time assessments.
- Clinicians' estimates of patient adherence have been shown to be inaccurate and should not be substituted for a thorough adherence assessment.

### Interventions to Improve Adherence

Clinicians should refer patients to substance use treatment programs to optimize patients' ability to successfully utilize and adhere to HAART and other medical therapies (Samet, Friedmann, & Saitz, 2001; Sorenson et al., 1998).

Adherence intervention strategies should include the following elements:

- Education and motivation, including treatment readiness, should be part of every visit
- If medically feasible, simplifying the regimen and tailoring it to the patient's lifestyle
- Preparation for and management of side effects
- Identification and treatment of depression and other psychiatric conditions
- Substance use treatment
- Involving an adherence team or monitor
- Referring the patient to social services and mental health providers for assistance in dealing with (or resolving) issues that are barriers to adherence

Clinicians and substance-using patients should work together to develop a plan to decrease or stabilize substance use in preparation for initiating ARV therapy.

**Key Point:**

Behavioral skills and motivation are crucial factors for promoting behavior change.

Table 2 Interventions to Improve Adherence	
Determinant	Action to improve Adherence
Beliefs and knowledge (of HIV medications)	Educate patient; provide information
Self-efficacy and adherence	Enhance motivation
Memory (difficulty remembering doses)	Offer patient visual aids to help remember daily regimen; use beepers, pillboxes, and other reminders

**CLINICAL ALGORITHM(S)**

None provided

**EVIDENCE SUPPORTING THE RECOMMENDATIONS**

**REFERENCES SUPPORTING THE RECOMMENDATIONS**

[References open in a new window](#)

**TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is not specifically stated for each recommendation.

**BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

**POTENTIAL BENEFITS**

- Improve the adherence to antiretroviral therapy among human immunodeficiency virus (HIV)-infected substance users
- Refer to Appendix A in the original guideline document for information on advantages of adherence measures.

**POTENTIAL HARMS**

Refer to Appendix A in the original guideline document for information on disadvantages of adherence measures.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
  - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
  - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
  - What steps need to be taken to make these activities happen?
  - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
  - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
  - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
  - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
  - Did the processes and strategies work?
  - Were the guidelines implemented?
  - What could be improved in future endeavors?

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness



## IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Adherence to antiretroviral therapy among substance users. New York (NY): New York State Department of Health; 2005 Jun. 11 p. [38 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2005 Jun

### GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

### SOURCE(S) OF FUNDING

New York State Department of Health

### GUIDELINE COMMITTEE

Substance Use Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### GUIDELINE STATUS

This is the current release of the guideline.

#### GUIDELINE AVAILABILITY

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

#### AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

#### PATIENT RESOURCES

None available

## NGC STATUS

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